DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 12, 2014

Oertli Instrumente AG
Ms. Karin Rohr
Head of Quality Management & Regulatory Affairs
Hafnerwisenstrasse 4
CH 9442 Berneck
Switzerland

Re: K133562
Trade/Device Name: CataRhex 3 Cataract Surgery System
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC, HQE
Dated: July 9, 2014
Received: July 11, 2014

Dear Ms. Rohr:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4: Indication for Use Statement

Indications for Use

510(k) Number (if known): K133562

Device Name: CataRhex 3

Indications for Use:

The CataRhex 3 is used for surgical interventions in the anterior eye segment.

- Irrigation and aspiration (I/A function)
- Ultrasound phaco (PHACO function)
- Bipolar diathermy for hemostasis and welding of the conjunctiva (DIA function)
- Diathermic capsulotomy (CAPS function)
- Operation of a vitrectomy instrument (VIT function)

The device may only be used with instruments recommended and supplied by Oertli Instrumente AG.

Prescription Use ___**X**____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for the CataRhex 3 Premarket Notification.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the CataRhex 3 is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate device.

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Contact:	Ms. Karin Rohr Phone: +41 71 7474275 Fax: +41 71 7474290 Email: karin.rohr@oertli-instruments.com
Date of Preparation:	November 16, 2013
Proprietary Name:	CataRhex 3
Common Name:	Phacofragmentation System
Classification Status:	Class II
Product Code:	HQC
Subsequent Product Code:	HQE, GEI
Panel:	Ophthalmic Devices

Predicate Device
Oertli's CataRhex 3 is substantially equivalent, for the purpose of this 510(k), to the following predicate devices.

510(k) Number	Clearance Date	Device Description
K081877	01/05/2009	ASSOCIATE 2500 DUAL AND COMPACT SYSTEMS
K101325	08/17/2010	STELLARIS PC VISION ENHANCEMENT SYSTEM

Device Description
The CataRhex 3 is medical electrical equipment to be used during eye surgery and is intended for ophthalmic anterior segment surgery.

It provides capabilities for phacoemulsification, phacofragmentation, diathermy coagulation, irrigation/ aspiration, vitrectomy and capsulotomy. The equipment has a display and buttons for selecting and activating the functions. With the equipment a footswitch is delivered for control by the surgeon.

Intended Use
The CataRhex 3 is used for surgical interventions in the anterior eye segment.
- Irrigation and aspiration
- Ultrasound phaco
- Bipolar diathermy for coagulation of bleeding during eye surgery
- Bipolar diathermic capsulotomy
- Operation of a vitrectomy instrument

The device may only be used with instruments recommended and supplied by Oertli Instrumente AG.

Clinical and Non-Clinical testing
The CataRhex 3 has undergone testing and is in compliance with applicable safety standards. The subject device was found to perform equivalently to the predicate device. Therefore, the subject device and the predicate devices have similar safety, effectiveness, and performance profiles.

No clinical studies were deemed necessary to determine the safety and effectiveness or substantial equivalence of CataRhex 3 to their predicate devices.

Conclusion

The technological characteristics that determine the functionality and performance of the CataRhex 3 are substantially equivalent to those of the predicate devices. The CataRhex 3 will be manufactured in compliance with FDA and ISO quality systems requirements. The data presented from the nonclinical tests demonstrate that the device is safe and effective, and performs as safely and effectively as the legally marketed predicate devices. Validation and verification demonstrates that the functional requirements and specifications have been met prior to commercial release.